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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,215	10/16/2001	Janice K. Albrecht	IN01344	5760

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/981,215	Applicant(s) ALBRECHT, JANICE K.	
	Examiner Shanon Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

The specification is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of nucleotide sequences greater than 10 nucleotides in the specification, see page 10, lines 8-11 in the disclosure for example. See 37 CFR § 1.821 (a)-(d) and MPEP § 2422.

Appropriate correction is required.

Claim Objections

Claims 9 is objected to because of the following informalities: The claim is awkwardly worded. The examiner realizes that the intent of the claim is intended to state that the amount of pegylated interferon alfa-2b administered is about 1.5 micrograms per kilogram per week on a weekly basis for at least 24 weeks. However, the claim language confusingly conveys this concept because the "treatment time period" could be interpreted as encompassing the dose administered in a week and not on a weekly basis for 24 weeks. It is suggested that applicant delete, "in the treatment time period" in line 3 of the claim to eliminate any ambiguity. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). at least 12 at least 24

Claims 1-3, 5, 7-9, 11, 14, 15, 20, 22, 26, 29, 31, 33, and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 9 of U.S. Patent No. 6,172,046 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to a method of treating HCV by administering a weight-effective amount of ribavirin and pegylated interferon alfa-2b. The range of weight-effective amounts of each component required to treat HCV is equivalent to the range amounts of each component recited in the patent to treat HCV genotype 1. Although the '046 patent does not expressly teach that the dose of ribavirin administered is based upon the weight of the patient, the patent requires that the doses of each component be "therapeutically effective", see line 29 of claim 1. In addition, the patent claims require that the amount of pegylated interferon alpha-2b administered is 0.5 to 2.0 micrograms per kilogram of patient weight, see claim 9. Therefore, the patent expressly teaches that weight is a factor to consider when determining dosage amounts for administration. One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the dosage of ribavirin based on specific criteria for each individual patient. One of ordinary skill in the art at the time the invention was made would have had a

reasonable expectation for optimizing the dose of ribavirin for each patient because the dose range of ribavirin recited in the patent is a therapeutically effective amount intended to treat any patient with HCV genotype 1. Therefore, the instant claims and the '046 patent claims are not patentably distinct.

Claims 1-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 9-13, 17 and 19 of U.S. Patent No. 6,472,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the range of weight-effective amounts of each component required to treat HCV is equivalent to the range amounts of each component recited in the patent to treat HCV.

Instant claims 1-3, 5-15, 20, 22-26 and 29-38 require administering a weight-effective amount of ribavirin and pegylated interferon alfa-2b to an HCV patient. The amount of ribavirin administered is "at least about 10.6 mg/kg of the patient's body weight" and the amount of pegylated interferon alfa-2b is 1.5 micrograms per kilogram of a patient's body weight. The amount of each component is combined to effectively treat HCV infection and the range of therapeutically effective dosage amounts instantly recited are equivalent to the range amounts of each component recited in the patent to treat HCV genotypes 1, 2 or 3. In addition, the patent claims require that the amount of pegylated interferon alpha-2b administered is 0.5 to 2.0 micrograms per kilogram of patient weight, see claim 7 and 17. Therefore, the patent expressly teaches that weight is a factor to consider when determining dosage amounts for administration. One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the dosage of ribavirin based on specific criteria for each individual patient. One of

ordinary skill in the art at the time the invention was made would have had a reasonable expectation for optimizing the dose of ribavirin for each patient because the dose range of ribavirin recited in the patent is a therapeutically effective amount intended to treat any patient with any HCV genotype.

Although the patent does not claim eradicating detectable HVC RNA for at least 12 weeks after the treatment period, the method of treating in the instant application and the '373 patent are equivalent. Therefore, any outcome resulting from the treatment method of '373, including a reduction in viral load, would be an inherent feature of the patented method.

Instant claims 4 and 21 state that the patient being treated by the instant method is infected with multiple HCV genotypes. Although the patent does not claim a method of treating a patient infected with multiple HCV genotypes, it is clearly evident from the claims that the patented method is therapeutically effective for treating genotypes 1, 2 or 3, see claims 1 and 10 for example. It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have been motivated to apply the method of '373 to treat an individual infected with HCV genotypes 1 and/or 2 and/or 3. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for treating an HCV-infected individual with multiple genotypes because the patent claims therapeutic effectiveness in methods to treat individual HCV genotypes with the same dose range of each component in the combination therapy, see claims 1, 2, 7 for treating HCV genotype 1 and claims 10-12, 17 and 19 for treating HCV genotypes 2 or 3.

Claims 16-19, 27, 28 and 39-42 state that the method involves treating a patient infected with HCV genotypes 2 and/or 3 wherein the patient has less than or greater than two million

copies of HCV per millimeter of patient serum. The '373 patent does not teach quantifying the HCV viral titer in a patient infected with genotypes 2 and/or 3. However, the patent teaches quantifying HCV-RNA titer of HCV genotype 1 infected patients and varying the treatment time period according to the amount of HCV-RNA present within the patient before treatment begins, see claim 1. One of ordinary skill in the art at the time the invention was made would have been motivated to quantify the HCV-RNA titer level present in a patient infected with HCV genotypes 2 and/or 3 to determine the severity of infection and administer the appropriate treatment time period to an HCV genotype 2 and/or 3-infected patient. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for adjusting the length of treatment time based on the concentration of HCV viral titer because '373 teaches varying the treatment regiment based on viral load.

In conclusion, the instant claims and the '373 patent claims are not patentably distinct.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
June 10, 2003